

AMENDMENTS TO THE SPECIFICATION:

Please amend page 1, paragraph 4, to read as follows:

BACKGROUND OF THE INVENTION

Endoscopic surgery, i.e., minimally invasive access to a cavity of a patient's body, such as the abdominal cavity, is typically performed through the use of miniaturized optical and surgical instruments. In the case of [the] laparoscopic surgery, which [involves] concerns the peritoneal cavity, the cavity is essentially virtual in the mind of the surgeon and cannot be explored by optical instruments. [In order t] To [give] provide the cavity with more substance, its walls are raised by insufflation[g] of gas, generally CO₂, to form a gas chamber, known as a pneumoperitoneum. Access to the pneumoperitoneal chamber is accomplished using trocars or small incisions that are fit with a valve, so that communication between the interior and exterior of the abdomen occurs without significant variation in actual pressure of the gas. Surgical instruments may then be inserted through the trocars and the optics connected externally to a [TV] television camera and, in turn, to a monitor, thereby forming a take and image transmission system.

Please amend page 2, paragraph 1, to read as follows:

Even if the pressure exerted on the patient's organs by the pneumoperitoneum facilitates spontaneous haemostasis of [the] countless capillaries [that are] as may have been lesioned in forming the pneumoperitoneum, it is considered necessary that perfect

haemostasis be achieved throughout. Otherwise, visibility inside the cavity may be so reduced ~~to such an extent that it may be as to make it impossible, or at least inadvisable,~~ to continue [the operation by] laparoscopic [procedure] surgery without [sacrificing] risk ~~to~~ the patient's safety. Normally, during [this type of operation] laparoscopic procedures, outflowing blood and [liquids] other bodily fluids are aspirated to keep the surgical site clean and ensure adequate instrument[al] visibility. [Unfortunately] While useful, aspiration is not only inefficient to implement, but it also [several seconds are] require[d]s serveral seconds to commence the aspiration process, which delay is unfortunately often decisive. As an alternative, [the] use of forceps to insert absorbent plugs [inserted] through a trocar at the surgical site [using a forceps] has been found similarly inefficient.

Please amend page 2, paragraph 2, to read as follows:

In one arrangement, an instrument is provided for inserti[o]n g [of] a haemostatic plug into the abdominal cavity during [a] laparoscopic [procedure] surgery. Such instrument includes a tubular element for receiving a plug of haemostatic material and a sliding plunger for applying the plug directly where bleeding has occurred.

Please amend from after paragraph 2 on page 2 to before the first full paragraph on page 3 to read as follows:

One disadvantage of these arrangements is that recovery of the plug using a forceps can be laborious and even dangerous, especially during laparoscopic surgery for the removal of a tumor. More specifically, [D]uring this procedure, the dissemination of cells, including those that may be cancerous, as is caused by partial squeezing of the plug as it passes through the trocar, may take place at a site far from that where the tumor developed [and can thus give rise to]. Such dissemination, in turn, may cause serious remote neoplastic dissemination which is difficult to treat. Because the plug becomes soaked with blood or other bodily fluids, there is also considerable risk that the surgeon may either be unable to find and remove the plug or simply “forget” the plug after it has been introduced into a patient’s body cavity. Such “oversights” often result in medical and legal disputes. While these disputes are generally less frequent in laparoscopic surgery than in traditional or “open” surgery, the risk is considered significant.

Please amend page 3, first fully paragraph, to read as follows:

OBJECTS AND SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a device for removing organic fluids from a body cavity of a patient during a medical procedure [so as to] that overcomes inefficiencies and delays attendant aspiration of such fluids, avoids the inefficient, laborious and hazardous nature of inserting absorbent plugs using [a]

forceps, and eliminates the risk of oversight associated with plug remov[ing]al [the plugs] during the procedure.

Please amend page 3, second full paragraph, to read as follows:

It is [A]another object of the present invention [is] to provide a device for inserting an absorbing plug into a patient's abdominal cavity during laparoscopic surgery, which [device] also allows the plug to be safely and easily located at the surgical site, thereby facilitating its recovery after use and avoiding the risk of its loss at the surgical site (and [of], hence, being left in the patient's body) as well as avoiding possible cell dissemination remotely to the site.

Please amend page 3, third full paragraph, to read as follows:

It is [A]a further object of the present invention [is] to provide a haemostatic plug that may be easily retrieved and recovered after use.

Please amend from after the third full paragraph on page 3 to before the first full paragraph on page 4, to read as follows:

According to one aspect of the present invention, a device is provided for removing organic fluids from a patient's body cavity during endoscopic surgery. The device comprises an absorbing plug, a tubular body suitable for slidingly housing the

plug, and a plunger slidably engageable in the tubular body so as to push the plug outside thereof and place it at the surgical site. The tubular body and plunger have a distal end and a proximal end. The plug is preferably connected to a radio-opaque plug locator that floats relative to internal organs, blood or other liquids present at the surgical site[.]. At the distal end of the plunger, a handle is provided for gripping the locator and recovering the plug after use by retracting the plunger inside the tubular body.

Please amend page 4, fifth full paragraph, to read as follows:

FIGS. 4a - 4c illustrate steps of a method for recovery of [the] a plug using the device shown in FIG. 1, according to one aspect of the present invention.

Please amend page 4, sixth full paragraph, to read as follows:

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings and, more particularly, to FIGS. 1 - 4c, there is shown generally a specific, illustrative, surgical device, in accordance with various aspects of the present invention. According to one embodiment, shown generally in FIG. 1, the device comprises a relatively rigid tubular sheath with open distal and proximal ends 1a and 1b, respectively. A proximal portion of the sheath is engaged proportionately firmly with a hub 2 having a handle such as [in the form of two] a plurality of diametrically opposing annular grips 3a, 3b generally coplanar to the sheath.

Please amend from after the sixth full paragraph on page 4 to before the first full paragraph on page 5 to read as follows:

A stem 4 is slidingly inserted in tubular sheath 1, the distal end of which preferably has an eyelet configuration [that,]. A[a]ccording to one embodiment of the present invention, the distal end is constructed of a flexible thin plate 5 bent in half so as to form a loop with its ends connected to distal end 4a of the stem via a transverse peg 6 (as best seen in FIG. 3). Advantageously, [in one embodiment,] plate 5 may be a strip of rectangular section and/or [may be] constructed of a selected harmonic or nickel-titanium steel to suitably exhibit sufficient flexural rigidity. Proximal end 4b of []stem 4 mounts an annular grip 7 which, in the present embodiment, is connected to the stem by a [steel] peg (not shown), e.g., made of steel, and co-planar therewith.

Please amend page 5, first full paragraph, to read as follows:

The tubular sheath and [the] stem are preferably made of a selected metallic or polymeric material suitable for surgical use, for example, polyethylene, TEFLON and/or the like. Annular grips 3a, 3b and 7 are [desirably] constructed desirably of a similar material. Circumferential grooves 11 are advantageously provided along stem 4 for housing O-rings (not shown) suitable for facilitating sliding along the internal lubricated surface of tubular sheath 1.

Please amend from after the first full paragraph on page 5 to before the first full paragraph on page 6 to read as follows:

The device, according to the present invention, preferably also comprises an absorbent plug 8 having an elongated shape and, more particularly, a substantially pear-shape, such shape being suitable for enabling its insertion in the tubular sheath. Plug 8 is ~~connected by a wire 9 joined to a ball 10 by a wire 9, the ball~~ (i) having a specific weight generally lower than that of blood such that it floats relative thereto, and (ii) being generally radio-opaque so as to be visible to X rays. The ball should preferably be colored so as to be visually identifiable within the surgical field and have a surface finish suitable for allowing blood to slide over its surface.

Generally speaking, [T]he plug can be made of any material suitable for haemostasis, and for [the] absorption of blood and any other liquid [which] that may be present in the surgical field. Beneficially, the plug may be constructed of polyvinyl alcohol (PVA) as in a product available under the commercial names MERACEL, IVALON or other equivalent products. Additionally, wire 9 is made of a biocompatible material, such as suture thread, having a diameter of about 0.5 mm and a length generally within a range of 8 cm and 10 cm.

Please amend page 6, first full paragraph, to read as follows:

~~Additionally, Wire 9 is made of a biocompatible material, such as suture thread, having a diameter of about 0.5 mm and length generally within a range of 8 cm and 10 cm.~~

Please amend page 6, second full paragraph, to read as follows:

The dimensions of ball 10 are such as to allow its insertion into tubular sheath 1 and, in turn, determine the dimensions of the loop so formed at distal end 4a of stem 4, which dimensions must necessarily be slightly larger than that of body 10. The ball must also be radio-opaque and white in color (or yellow, or another light color) so as to be easily identified at the surgical site. Optionally, a plurality of additional balls [may be] are provided[, in addition].

Please amend page 6, third full paragraph, to read as follows:

~~Desirably, the length of the stem is greater than or, at most, equal to that of the tubular sheath to ensure that eyelet end 4a of the stem projects fully from the sheath when the stem is fully inserted therein.~~

Please amend page 6, fourth full paragraph, to read as follows:

In [order] operation, to locate the plug at the surgical site, tubular sheath 1 of the insertion device, where the plug had been placed previously, is introduced into the patient's abdo[-]minal cavity through a trocar. By sliding the stem, which operates like a plunger, the plug is pushed outside of the tubular sheath and located by the surgeon at the desired place of use. In this regard, it is considered desirable that the length of the stem be greater than or, at most, equal to that of the tubular sheath to ensure that eyelet end 4a of the stem projects fully from the sheath when the stem is fully inserted therein.

Please amend from after the fourth full paragraph on page 6 to before the first full paragraph on page 7 to read as follows:

Once the plug has served its function, it must be recovered and removed from the abdominal cavity. To this end, as shown in FIGS. 4a, 4b and 4c, initially ball 10 is identified visually. Eyelet end 4a of the stem is then moved toward[s] the ball such that it passes suitably through the loop and hooks wire 9 of the plug. Next, through light hand movements of the surgeon, the loop is caused to slide along the wire, pulling the stem backward[s], generally in the direction of arrow F in FIG. 4c, until the plug has returned to a position completely inside the tubular sheath. Thereafter, the device is disengaged from the trocar.

Please amend page 7, first full paragraph, to read as follows:

Overall, the present invention is [especially] particularly advantageous in that recovery of the plug and, more particularly, its reinsertion in tubular sheath 1 after use, is performed directly at the surgical site, so that partial squeezing of the plug, as inevitably occurs during use, [is] does not become a source of remote contamination. Contamination is [particularly] especially dangerous during removal of a tumor, namely, when tumoral cells are present, given the possibility of neoplastic dissemination and the risk of formation of metastasis. More specifically, partial squeezing of the plug, as a worst case scenario, is tantamount microscopically to incomplete removal of the tumor. Inevitably, with or without the plug, while this may still give rise to the possibility of a relapse of the disease locally, it is preferred when compared to the severity of remote metastasis.

Please amend page 7, second full paragraph, to read as follows:

[Furthermore] Moreover, the loop hooking device of the present invention is considered highly desirable [for] due to its simplicity and effectiveness. As those skilled in the art will appreciate, based on a review of this disclosure, other equivalent hooking devices may be utilized within the spirit and scope of the present invention.